Exhibit B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION,	) MD No.: 02641

VIDEOTAPED DEPOSITION OF CHAD MICHAEL MODRA

Phoenix, Arizona

December 15, 2015

9:06 a.m.

REPORTED BY:

Robin L. B. Osterode, RPR, CSR

AZ Certified Reporter No. 50695

Q. Okay. And when you say you re -- you reviewed those documents, precisely what are you speaking about?

A. Well, I was involved in writing pretty much all of them. So it was more of a refreshing my memory on those.

Q. Okay.

A. On the warning letter response, the warning letter, and the responses since that time.

Q. Okay. I'm going to come back to this list on Exhibit B as we get a little farther, so I can make sure that you and I are on the same page with respect to what's requested here.

Have you had your deposition taken in the past?

A. I have.

Q. About how many times?

A. Twice.

Q. All right. And you have, from that experience, some understanding of the process, that is, the question-and-answer process?

A. Yes, I do.

Q. It's -- let me just offer a couple thoughts. It's important that you answer only questions that you understand. Okay?

Q. Who was the vice president immediately before you?
A. Ms. Gin Schulz.
Q. Where is Ms. Schulz now, in terms of corporate employment?
A. She is the vice president of quality at our corporate offices. She's my boss.
Q. And in terms of your own organizational chart, immediately below you on the org chart, who is immediately below you, your direct report?
A. I have three directors.
Q. Who are they?
A. Scott Neal, our director of quality engineering. Ms. Maureen Uebelacker, director of quality assurance. And Elliott Doppelt, director of quality systems.
Q. How is Elliott's last name spelled?
A. D-o-p-p-e-l-t.
Q. Did Ms. Uebelacker, then, take the director's job which you vacated in order to become the vice president?
A. No. No.
Q. Who filled the spot you vacated?
A. There wasn't a spot vacated; it was changed from a director position to a vice president

A. Yes.
Q. And in the middle of that, in July, is this warning letter?
A. That's correct.
Q. Okay. And do I understand that you, by the nature of your job, your title, your responsibility, are kind of smack dab in the middle of responding to the 483s, all the way up through whatever's going on at present?
A. I am very much involved in all of it.
Q. Is there anybody who knows more about the process than you? And I'm talking subjectively, in your own mind?
A. Subjectively, I don't think so.
Q. Okay. And that's not -- we're not denying the fact that there might be somebody who thinks they do?
A. Yeah, that might be their opinion.
Q. Those people are everywhere, in all walks of life.
A. Yes.
Q. Okay. Then back to the not very good question I asked a moment ago. You come here to Arizona; you're changing the focus of your job. Right?

(Interruption of proceedings.)
BY MR. KELLY:
Q. That's how scintillating my question is. The first person has dropped off, Mr. Modra. There's a pool at the end of the table of how many will be gone within the next 30.
MR. NORTH: I'm sorry to interrupt, but there have been a lot of people join since we gave the instructions on e-mailing for appearances. It might be helpful if you repeated that, Ramon.
MR. STOLLER: It went out to the group.
MR. NORTH: It did?
MR. LOPEZ: Yeah, we sent an e-mail out to the group.
MR. NORTH: Thank you.
BY MR. KELLY:
Q. Now, with respect to the -- the group -- and I'm assuming something here I don't want to do that.
So in your job, do you work as a team? Do you have a team?
A. Yes.
Q. Okay. And on your team whose focus is quality assurance, including post-market surveillance and trending, investigation, et cetera, who's on the

team?

A. That would be my director of quality assurance and her reports, the managers for the investigation of the complaints, complaint handling.

Q. All right. And so I know you gave me that name earlier. Does it begin with a U?

A. Maureen Uebelacker.

Q. Uebelacker?

A. U-e-b, elacker.

Q. I've got it phonetically.

A. Yeah.

Q. And her managers are whom?

A. John Wheeler and Judy Ludwig. Yeah.

Q. And I will tell you that I've reviewed some of the materials that have been produced from the 483 notice forward, and those are names which appear more than once, so --

A. Yes.

Q. -- how is it that some part of the investigation and analysis and response of the notification from the FDA and the correspondence that's gone back and forth fell into their areas of responsibility?

A. Under my direction, you know, we have to have people working on smaller bits to certainly

Q. All right. And as the vice president of quality, you had the responsibilities and continue to have the responsibilities for complaint investigation, for trending, for compliance with FDA regulations, for making sure that you are correctly tracking and monitoring injuries, deaths, et cetera?

MR. NORTH: Objection to the form.

THE WITNESS: I do for the manufacturing facilities that now report to me. The divisional responsibilities as of two weeks ago report to a new person.

BY MR. KELLY:

Q. Okay. But as of two weeks ago --

A. Yes.

Q. -- you had those responsibilities I just outlined?

A. That is correct.

Q. And had them throughout the time of the various periodic responses?

A. Yes, that's correct.

Q. Who's taken that responsibility? Who's moved into that job?

A. Garth Conrad.

Q. And where is Mr. Conrad from, geographically?

Q. Right. And had you seen one of these before, that is, one of these forms, the 483 reports?
A. I have seen them before.
Q. And she, on the very last page, has a number of days listed here, dates of inspection. If I'm understanding an earlier answer, she was not actually at your facility each of these days; is that what you're telling us?
A. That's correct.
Q. And this documents the days, apparently, she spent at whatever location looking at these complaint files?
A. Yes.
Q. All right. In addition to complaint files, was she given access to other information, including did she request standard operating procedures, work instructions, quality systems guides, et cetera?
A. Yes, she did.
Q. And so, again, in terms of that list, who is she dealing with to get that information?
A. It would either be myself and/or Scott or Maureen, primarily.
Q. And so for some of the time that she was at your facility, were you back from Glens Falls?
A. Upon her arrival, I immediately booked a

A. Well, with Observation 1, she's citing, one, the incorrect completion of the form, and then on the other ones she's citing that those, in her opinion, as an FDA representative, should have been reported as serious injury versus a malfunction, both of which are reportable events, but in either case, as far as our trending and tracking, those -- that's important information, but we're conducting that tracking and trending, regardless of whether it's reportable or not.

Q. Let me just ask about this particular first one, 562535, the -- among the things that the investigator tells you, and I'm going to make sure I have this right, this is a file that got closed?

A. Correct.

Q. And it got closed with the FDA being told the patient had a serious injury?

A. I believe so, yes.

Q. Right. And the FDR gets -- the FDR --

A. FDA.

Q. By the way, he will not be attending this deposition.

The FDA gets a two-page form; is that right?

A. Yeah, Form 3500A.

A. I believe so, yes.
Q. Okay. And -- and their respective titles are --
A. Field assurance -- senior field assurance manager and director of quality assurance.
Q. And the senior field person is Maureen?
A. It is Judy. I'm sorry.
Q. All right. And the director is Maureen?
A. That's correct.
Q. And do they actually have responsibility for teaching people how to correctly do complaint investigation and fill out the forms?
A. That's correct.
Q. All right. So if we could just go to the second page under B, again, in the 483 form, and just so we're clear, ultimately, these individual examples -- you understand these are examples?
A. Yes.
Q. All right.
-- are ultimately referenced as well in the July letter; is that right?
A. I believe they are, yes.
Q. In fairness to you, it's not a trick question, the one we just mentioned. So if you go to -- would you tell me what number that is?

bottom of this, who were the best people that you put together on your team?

A. I involved those involved in preparing those files as well as, you know, K&S, King & Spalding.

Q. No, no. I mean, I'm limiting myself here. You have a team of people who are working with you day by day in field assurance and quality assurance. Correct?

A. Correct.

Q. King & Spalding is not working with you daily on field assurance and quality assurance?

A. No.

Q. And neither is Hogan and Lovells?

A. No.

Q. Or any other lawyers or law firms?

A. No.

Q. So I'm focused here on, okay, we're here in Tempe; I want my best people on the ground looking at this; I'm going to assemble a group. Did you do that?

A. Yeah.

Q. And did you have, actually, physical meetings and take notes and make minutes and have e-mail correspondence back and forth about here's how

we're going to approach this?

A. We opened up a CAPA, a corrective action -- corrective and preventative action document, and we -- it's all documented in there, brainstormed, thought of, you know, reviewed other regulatory documents, reviewed other literature, tried to understand not just this particular situation, but was there anything else where we were -- that we needed to improve on. And we documented it in the CAPA.

Q. Okay. I get all that. And the team of people that you put together to do that --

A. Uh-huh.

Q. -- did you appoint yourself as the head person or did you appoint someone else to direct and oversee the CAPA root cause analysis, et cetera?

A. I ultimately have to agree with it, and help guide it, make sure that we're capturing all possible root causes, and primarily Maureen, Judy, and others were involved.

Q. And when you say "and others," were there others at the management level who were involved?

A. Not in particular.

Q. Okay.

A. These were field assurance-related, so I

independent medical knowledge when they take the job. True?

A. True. That isn't true of all of them. We do employ nurses and others and we have, again, the clinical oversight in that group to provide that knowledge to them.

Q. And so any time they see that there's a broken piece of one of these IVC filters that's lodged in a place other than where it's supposed to be, they're supposed to go and figure out, from the information you gave them, what the potential consequences to human health would be; is that what you're telling us?

A. That's part of the review.

Q. A mandatory part of the review?

A. Yes.

Q. Because you want them to have complete, full, and thorough understanding of whether this is a serious injury?

A. Yes.

Q. And whether it's a serious injury is going to depend upon how it's going to be retrieved, whether it poses a risk to life or permanent injury, et cetera, as per 803?

A. Yes. But whether it's a serious injury or

a malfunction, it's -- they're all required to be investigated, and we do that. We trend them and they're based on the failure event, like the code that's designated as part of the event, not -- not just because it's a serious injury or not; it's independent of that.

Q. All right. And that actually wasn't the question I asked, but I'm happy to ask it. If something is a malfunction, are they supposed to determine whether or not this poses a potential risk? They think it's a malfunction; are they supposed to determine is this a potential risk to a human being's well-being?

MR. NORTH: Objection to the form.

THE WITNESS: To go through the checklist and determine the impact on the patient --

BY MR. KELLY:

Q. I'm not asking about the checklist. I'm asking whether they are supposed to access this encyclopedia of information you described earlier. Are they supposed to go and find that out?

MR. NORTH: Objection to the form, argumentative.

THE WITNESS: The checklist, as I referenced, was the decision process with which they

BY MR. KELLY:

Q. Do you have that in writing?

A. Yeah, I have it in meeting minutes and writing.

Q. And that came in the December 8th letter?

A. No.

Q. You received a letter just recently from FDA, didn't you?

A. Yeah. Yesterday.

Q. And yesterday did they tell you it's all right not to report failure to deploy?

A. They made no mention of disagreeing with those. They're not going to say until they come back for a reinspection.

Q. Did they say you don't have to report a failure to deploy in the December 8 letter?

A. They did not say that in the letter, but they did say it in correspondence with our medical director.

Q. Did they say it in their July 2015 letter, you don't have to report a failure to deploy?

A. No, what -- what they -- we've come to realize is what they were saying here was not that they have to report failure to deploy, but that they wanted more information and justification why we did

not report these.

Q. Whatever they said is what they said in the paper. Correct? I mean, they were clear about what they said?

A. By definition.

Q. All right. And they were clear enough so that you spoke multiple times with various law firms about what your appropriate response should be. Correct?

A. Uh-huh.

MR. NORTH: Objection to the form.

BY MR. KELLY:

Q. How many times do you think you've talked to lawyers about what your response should be with respect to the individual responses given between January 1, 2015 and August of 2015?

A. I don't know the exact number.

Q. Please give us your best estimate. Would it be in the hundreds of times?

A. I don't know about hundreds of times, but yeah, numerous times.

Q. What does "numerous" mean?

A. Two dozen, three dozen, probably.

Q. Okay. Would it have been more than one time for each letter?

A. No.
Q. Okay. So is it fair to say nobody who is copied on this letter or to whom the letter was directed was a member of the quality assurance department here in Tempe?
A. Not a direct member, no.
Q. Okay. Well, do you report at all to Mr. Walaska?
A. No.
Q. As you were preparing your periodic updates, were you looping in Gin Schulz?
A. I was -- in some cases, yes; some cases, no.
Q. And how would you do that? Would you send her an e-mail to let her know what was going on?
A. I would typically call her.
Q. Okay. Do you believe there's also e-mail correspondence between you and Ms. Schulz regarding any of the periodic updates or the responses to FDA?
A. I'm sure there are some.
Q. And, similarly, with respect to trying to find out what are best practices for the company, talking to various folks, would you have brought her up to date on what you were learning?
A. They have experience, with Bard certainly,

but then other companies, so I may have sought their advice.

Q. But in terms of bringing her up to date on what you were learning --

A. Uh-huh, yes.

Q. -- is that something you would have brought her up to date on?

A. Yeah. Yeah.

Q. Let me -- so for each of these items under so-called Observation 1, A, B, C, D, E, F, G, H, for each of these, was, in fact, it determined that they should have been reported as a serious injury?

A. That is what they state.

Q. And on -- on your end, when you looked at this, as people interested in quality and patient safety, did you determine, upon seeing these, that these should have been reported as a serious injury?

A. That is how we responded, yes.

Q. But regardless of how you responded, did you look at these and say, you know what, they're right; these were serious injuries that should have been reported?

A. In their understanding, yeah.

Q. In your understanding?

A. Uh-huh.

Q. Yes?
A. Yes.
MR. NORTH: Objection to the form.
BY MR. KELLY:
Q. And so when you got this at the closeout meeting, and saw that, you know what, it looks like, one, two, three, four, five, six, seven, is it eight, is that right, A, B, C, D, E, F, G -- we've got eight things that were not reported as serious injuries out of 43, were you upset by that?
MR. NORTH: Objection to the form.
THE WITNESS: I was very concerned.
BY MR. KELLY:
Q. And were you very concerned, why?
A. Because I wanted to make sure that we're meeting expectations of FDA, and that we're filing these in accordance with those expectations.
Q. And were you also concerned that the mischaracterization, whether serious injury or malfunction, would, in fact, impact your risk analysis for whether people were getting hurt?
A. No.
MR. NORTH: Objection to the form.
BY MR. KELLY:
Q. And why not?

A. Because the FMEA and -- reportability is, in some cases, independent of the risk analysis that we do. The trending that we do, whether or not we would take an action, a field action, or even, you know, correction, a recall on a device, it's -- it's based on the event code, which is the event that's reported, and the severity that's tied to FMEA, not whether or not they're reported or not.

Q. So did you tell the FDA for each one of these we've actually done an FMEA risk analysis where we decided in-house that these were serious injuries, but we did not tell you?

MR. NORTH: Objection to the form.

THE WITNESS: It wasn't that -- you make it sound underhanded, and that wasn't the case at all. These were reported to FDA, and we had done the analysis; they're included in trending. We've evaluated each and every one of those for its impact on the patients.

BY MR. KELLY:

Q. So even though you didn't tell FDA it was a serious injury for complaint A, had you trended it in-house as a serious injury for part of FMEA analysis?

MR. NORTH: Objection to the form.

THE WITNESS: You wouldn't trend it just based on serious injury. You trend it based on the actual event. So whether it's characterized as a serious injury or a malfunction or something else, they're evaluated by the severity of the event, so regardless of what they're reported as, they are trended and tracked and actions are taken accordingly.

BY MR. KELLY:

Q. Okay. Even though you told FDA that complaint A was a malfunction, did you trend it internally as a serious or severe injury?

MR. NORTH: Objection to the form.

THE WITNESS: Yes.

BY MR. KELLY:

Q. You did?

A. Well, there -- it's not trended on just because you check the box and it's serious injury; you trend it on the event, the code that's associated with the event.

Q. So you had a code that told you internally, in case A, this is a severe injury. Correct?

A. At the start, but then when it was trended to, or I'm sorry, when we got more information and it was changed to death, then it would have been

Q. I'm talking here about physical injuries. I'm not talking about malfunctions. You certainly want to track and trend physical injuries, yes?

MR. NORTH: Objection to the form.

THE WITNESS: I want to track and trend all complaints, not just physical injuries, because I want to understand all of them.

BY MR. KELLY:

Q. I understand that, sir.

A. Sometimes you take action, not just based on whether they harm somebody, but whether there's the potential to. There may be never an injury, but we might take action --

Q. Exactly. Exactly. Sometimes you take action before anybody gets hurt. Right?

A. Sometimes.

Q. And, really, that's ideally what you'd like to do, prevent the first person from getting hurt. Correct?

A. Yes.

Q. And once you find out people are getting hurt, you want to be even more vigilant in trying to prevent it. Correct?

A. I don't know if it's any less or more vigilant. It's the same level of vigilance.

spreadsheet?

A. No.

Q. All of this work was done by you and your team with the aim of trying to produce a good, safe, and efficacious product. Correct?

MR. NORTH: Objection to the form.

THE WITNESS: With the purpose of making sure that we were compliant in the eyes of FDA, as they cited us in the 483.

BY MR. KELLY:

Q. Sir, first and foremost, this is all about making sure that the product is safe, isn't it?

A. This -- this reporting here, what's about making the product safe is the tracking and training we do regardless of whether it's reportable or not. If we only relied on the assumption that it's only the FDA that can catch somebody from doing something with a device, that's a -- that's a bad assumption.

Q. It's a horrible assumption, because the primary responsibility to track and trend is on you and Bard?

A. That's correct. And independent of the filing of these, we tracked and trended --

Q. Exactly.

A. -- based on the code.

Q. It's the same definition that we're using for all of these?
A. Yes. It includes --
Q. And now we have brand-new, never-discovered-before 38 new serious injuries?
MR. NORTH: Objection to the form.
THE WITNESS: They were reported as serious injury.
BY MR. KELLY:
Q. And you have to believe at this point in time, after the FDA has been there, folks are being careful in what they're reporting. Correct?
A. Yes.
Q. They're being precise and they're doing it right by the book. Correct?
A. They were doing it based on their understanding of the book prior to that.
Q. Well, but by now, you're absolutely making sure that the reports are correct and accurate. Can we agree on that?
A. Well, as part of this review, we also expanded the definition of what we would consider or what anyone would reasonably consider serious injury. So we did go ahead and file those as serious injury, and we've -- based on the OSB meetings we've had

recently, have come to understand that FDA has told us that they would not file those as serious injury.

Q. How many of those 38 would the FDA have not filed as serious injury, sir?

A. I don't know.

Q. Well, how would you figure that out?

A. We would have to go back and look and see which ones, based on the OSB comments that we had, would no longer be reported as serious injury.

Q. We would have to walk through each one of those complaint files together. Correct?

A. I'd want to do it with a -- one of our clinical specialists.

Q. Would you want to do it with one of the lawyers from Hogan and Lovells or from King & Spalding?

A. No, because we have now we have guidelines that we agreed to with OSB, so they're -- they provided us greater clarification on what they want reported.

Q. Now, sir, with respect to these 44 new ones, did anyone go through those files with eyes on and determine whether they were correctly coded, in terms of the event codes internally?

A. It doesn't state that in this memo.

A. Correct.

Q. All right. But you've not done that and you can't tell us here how many in that time period, how many MDR serious injury reports were filed for this batch of complaints?

A. I don't know offhand, no.

Q. In real life, if you wanted to get the answer to that, not that this is not real life, but in practice, sitting in your office, is that something that you would delegate to somebody else who is more facile with the database in terms of being able to query it and search it?

MR. NORTH: Objection to the form.

THE WITNESS: I would ask one of the specialists or engineers.

BY MR. KELLY:

Q. Okay. And who is the person that you would most likely ask?

A. One of the engineers, it could be Ryan Brunet or Judy. I might just ask Judy, because she's the supervisor, so then she can delegate it to who -- who has time.

Q. Now, if I'm understanding this correctly, the search was done on that part of the complaint file that's described -- oh, what the heck did I do

records, doctors' information would have been queried with these search terms?

A. Not directly, because those are attachments to the file.

Q. Correct.

A. They're often quite large, so the narrative of those, I know we spend a lot of time bringing that narrative into the parent record of the complaint, and then that's part of the search.

Q. And do I understand from that that if the individual complaint reviewer inputted some data or summarized data out of the medical records into the investigation file, that's the way it gets there, in terms of this search query?

A. We have the clinical specialists are the ones that do the medical record review.

Q. Okay. Now, having turned up this number of 29 percent that required modification or -- and a supplemental report or a brand-new report, was there any discussion about, hey, let's query some more search terms?

A. There wasn't, because many of those events that you're noting there included things that -- that hadn't reported any sort of injury; it was for the potential to cause the injury.

Q. Okay. Sir --
A. And in some cases I know that they said there was no relationship to the device itself, but we cast a pretty wide net.
Q. But I'm wondering when you had 29 percent inaccuracy for which you made the change -- you would not have made changes if it wasn't authorized, would you?
A. In the interest of casting a wide net and being overly reporting, which we've come to find out we have been over reporting.
Q. So have you cut back on your reporting?
A. No. No. With OSB, after those discussions again, we, I guess, after they told us that those -- a number of those would not be reportable, going forward we'll report those as OSB has stated.
Q. So with respect to these search terms, I note, for instance, you certainly -- actually, let me go back, when you did these search terms, did you look at the individual complaint files identified by Ms. Perkins to see if in the selection of these search terms you had identified all of the actual or potential patient injuries in the file sheet you looked at?
A. We did.

where you have, in response to another issue, under the heading "Completed actions." Do you see that?

A. Yes.

Q. I'm at the bottom of the page, in the middle paragraph?

A. Yes.

Q. It says "We opened CAPA, VT-CAPA-15-002, on January 23, 2015 to the issues raised in the Form 83 observations." Some questions about the CAPA process?

A. Yes.

Q. Is this a -- the acronym is corrective action?

A. Corrective and preventative actions.

Q. Corrective and presentative actions.

And this -- the decision to open this corrective and preventative actions plan was whose decision?

A. Ultimately mine, but that -- that's expected as part of the response.

Q. But this was not intended to be an idle act on your part, was it?

A. No.

Q. And it wasn't simply intended to placate the FDA?

your recent promotion; in other words, was that consistently true?

A. True, and even beyond that.

Q. Okay. I'm looking for a moment here at March 26, 2015 periodic update. Actually, you know what, let's do February and March, and do them in chronological order since that makes more sense. Yeah, so there's two -- let me put this down -- I guess we need to print these, so they're going to print them.

Let me ask you a couple of other things from when we began this morning. In the -- in the exhibits to today's deposition, there was a list of things, and I'd like to walk through them, if I might, with you. I think that was the Exhibit Number 1. And when we look at category number 2, the communications with the FDA relating to the warning letter, and that contemplates from the 483 up until the present.

Who are the folks that have had communications with FDA from Bard?

A. Myself, folks from GFO.

Q. Which folks from GFO?

A. Jason Gaede, Gin -- no, I don't think she has. Patty Christian.

process.

Q. My question is, who are those people?

A. It isn't just one particular person.

Q. That's why I asked who are those people?

A. Okay. It's part of the management review process --

Q. Who are --

A. -- of the facility.

Q. Who are the people in the management review process at the facility who are analyzing and making the decisions about the significance or insignificance of the trending?

A. It's the management board, myself, the head of regulatory, the head of operations, marketing, sales, international finance.

Q. And in that group, is there an epidemiologist?

A. I don't believe any of them are epidemiologists.

Q. Is there a statistician?

A. I don't think so.

Q. Is there a physician?

A. No.

Q. And do the people who head up marketing and sales have any training as doctors or health

A. But that's not the entirety of all the folks that look at that information.
Q. But in terms of on whose desk the buck stops for decision making, it's a board call?
A. It's part of the management review process, so yes.
Q. And the board meets with what frequency?
A. At least once a month.
Q. And when you meet, do you traditionally meet in person or on the phone or a combination?
A. Typically, in person, but occasionally on the phone.
Q. And the meetings typically are where?
A. Here in Tempe.
Q. Do you still have a board-level position with your new job?
A. No. Because I'm not associated with a -- a division.
Q. So you're going off the board?
A. That's correct.
Q. Okay. Now, with respect to the person who is taking your place, they're coming onto the board or not?
A. Yes, they are.
Q. And with respect to how the trending data

is circulated, is it done, for lack of a better term, automatically? That is, each month it's just generated or each week or each day to each of these people on the board?

A. I -- we compile a packet of information and I take the time and walk through it, and describe what we've seen, discussing the results, answering questions, taking actions.

Q. Now, you have multiple products besides IVC filters?

A. That's right.

Q. And, therefore, there is trending information to be shared about all of the products; is that right?

A. Yes.

Q. And do you actually walk through the trending information on all products at each meeting?

A. Yes.

Q. And is it your custom and practice to send out a report, whether -- a report in connection with the trending for each meeting?

A. I don't know about "send out." I do print copies for each person.

Q. You print copies?

A. (No audible response.)

approximately 5:42 p.m.

E X A M I N A T I O N

BY MR. LOPEZ:

Q. All right. Well, I hear we've got 20 minutes left. Ramon Lopez, I also represent the plaintiffs. I've been designated to deal with the portions of this warning letter that basically have not been covered much, if at all yet, and that is violation -- and these are violations. Right?

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. In the warning letter?

A. They're stated as violations in the warning letter.

Q. Right. The fact that it says "these violations include, but are not limited to the following" and number 1 is the -- deals with the Recovery Cone and the adulteration and misbranding violations at the Tempe, Arizona facility. Correct?

MR. NORTH: Objection to the form.

THE WITNESS: That's what it states.

BY MR. LOPEZ:

Q. And then violation number 4 is "A quality system regulation violation at the," excuse me,

"Queensbury, New York facility. Failure to validate with high degree of assurance and approved according to established procedures and manufacturing process that cannot be fully verified by subsequent inspection and testing, to ensure the process will continue to meet specifications as required by 21 CFR 820.75(a)." Correct?

A. Correct.

Q. Do you want a copy of the warning letter just to have it in front of -- do you have it in front of you there?

A. No, they took the copy.

THE REPORTER: I didn't take it. It's right there.

THE WITNESS: Oh, okay, sorry.

MR. LOPEZ: Those are the extra copies, the five copies that Karen brought down. Yeah, I just want to give one to the witness. Thanks.

Q. Yeah, I'm on page --

A. Does this need to be a number?

Q. No, no, go to page 5 of the warning letter.

A. Okay.

Q. And that's, what I just read, that's violation number 4. Do you see that? That's the one I just read.

A. That's correct.

Q. Okay. Then if you go to two pages beyond that, page 7 of the warning letter. You see violation number 5?

A. I see number 5, correct.

Q. "Failure to establish and maintain procedures for acceptance of incoming product and to inspect, test, or otherwise verify incoming product as conforming to specified requirements as required by 21 CFR 820.80(b)." Right? That's the violation number 5?

A. Correct.

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. And then I won't read number 6, because we don't have time, but then you see violation number 6 is another failure that deals with procedures to ensure that all purchased or otherwise received products conform to specified requirements, et cetera. Correct?

A. Correct.

Q. Now, going back to violation number 1, that deals with the Recovery Cone. The first thing I should ask you is, do you think you're the appropriate person at Bard to speak on behalf of the

was the approval, or I'm sorry, clearance.
BY MR. LOPEZ:
Q. It was -- I mean, I guess I can keep reading this over and over again, but FDA, again, its position is that that really didn't happen. It should have been -- it was not marketed with the required clearance or approval. Right?
A. That is what they state.
Q. Who else? How about Susan Alpert, Susan Alpert was involved back in the day, right, when this thing was going through its testing and when the Recovery Cone first got on the market?
A. I haven't seen her name on it or been aware of her involvement in this.
Q. Now, let me ask you, is this device still being marketed or not in the United States today?
A. It is, in an agreement with FDA, because of its necessity for removal.
Q. Explain that to me?
A. We work very closely with FDA, answered a number of their questions related to clarifications on it, and they agreed with the assessment that it's important to, while the 510(k) is being reviewed, to keep it on the market for removals.
Q. Now, what does that mean keep it on the

A. It is.

Q. And in other words, it's not part of -- if somebody gets a Recovery Cone or a G2 or an Eclipse or whatever filter device that this is intended to remove, that -- this particular device is not included in that kit. True?

A. True. Because the person removing it may not be the person placing it.

Q. Exactly. In other words, this is its own device?

A. Correct.

Q. And it has its own IFU?

A. Correct.

Q. Right? And it has its own warning section -- on the left -- it has potential com -- there you go, warning section, precautions, and then on the other side it has potential complications listed. Those all apply to this device?

A. Correct.

Q. All right. So you think a device that has all of these potential warnings and precautions and potential complications should have ever been considered a Class I device by you, by Bard?

MR. NORTH: Objection to the form.

THE WITNESS: It was determined as a -- or